K062195

OneTouch® Ultra® Blood Glucose Monitoring System

510(k) Summary

AUG 16 2006

Submitter

LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035-6312
510(k) Contact: Cindy Morrow, LifeScan, Inc.
Alternate 510(k) Contact: Mary Ellen Holden, LifeScan, Inc.

Device Name

OneTouch® Ultra® Blood Glucose Monitoring System
Common name: Glucose test system
Classification:

(1) OneTouch® Ultra® Blood Glucose Meters and OneTouch® Ultra® Test Strips are Class II devices (21 CFR § 862.1345)
(2) OneTouch® Ultra® Control Solution is a Class I device (21 CFR § 862.1660)
(3) OneTouch® UltraSoft® Adjustable Blood Sampler with OneTouch® ClearCap™ and OneTouch® UltraSoft® Sterile Lancets are Class I (exempt) devices (21 CFR § 878.4800)

System Description

The OneTouch Ultra Blood Glucose Monitoring System consists of the OneTouch Ultra Meter, OneTouch Ultra Test Strips (provided separately), OneTouch Ultra Control Solution, OneTouch UltraSoft Blood Sampler with OneTouch ClearCap and OneTouch UltraSoft Sterile Lancets. The predicate OneTouch® Ultra® meter hardware and software has been modified. There are no changes to other system testing components compared to the currently marketed product.

Predicate Device OneTouch Ultra Blood Glucose Monitoring System

Intended Use

The OneTouch Ultra Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose in fresh capillary whole blood. The OneTouch Ultra System is intended for use outside the body (*in vitro* diagnostic use) by people with diabetes at home and/or by healthcare professionals in a clinical setting as an aid to monitor the effectiveness of diabetes control. The OneTouch Ultra Blood Glucose Monitoring System is specifically indicated for use on the finger, forearm or palm.

Comparison to Predicate Device
The modifications to the device encompass meter hardware and software/firmware changes. The labeling has been updated to provide electrical safety testing certification in accordance with ISO 15197:2003(E). There has been no change to the intended use, operating principle, functionality, or material composition of the device.

Technological Characteristics
There has been no change to the fundamental scientific technology.

Summary of Performance Characteristics
There has been no change to the performance characteristics of the system.

A system accuracy study demonstrated that the modified OneTouch Ultra Blood Glucose Monitoring System and the currently marketed OneTouch Ultra Blood Glucose Monitoring System are substantially equivalent.

Design Verification (including software verification and validation testing) confirmed that the performance, safety and effectiveness of the modified OneTouch Ultra Blood Glucose Monitoring System were equivalent with that of the predicate device.

The modified meter was tested in accordance with ISO 15197:2003(E) including system accuracy and electrical safety testing. In addition, testing was performed to verify the effectiveness of the changes to the meter hardware and software.

Conclusion
The modified OneTouch Ultra Blood Glucose Monitoring System is substantially equivalent to the predicate OneTouch Ultra Blood Glucose Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 16 2006

Ms. Cindy Morrow
Sr. Regulatory Submission Specialist
LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035-6312

Re: k062195
Trade/Device Name: OneTouch® Blood Glucose Monitoring System
Regulation Number: 21 CFR§862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: July 31, 2006
Received: August 1, 2006

Dear Ms. Morrow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062195

Device Name: OneTouch® Ultra® Blood Glucose Monitoring System

Indications For Use:

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The OneTouch Ultra Blood Glucose Monitoring System is specifically indicated for use on the finger, forearm or palm.

Prescription Use ____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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